COLORADO
Department of Health Care Policy & Financing

1570 Grant Street
Denver, CO 80203

Health First Colorado (Colorado's Medicaid Program) Coverage Standards for CAR T-Cell Therapy

June 2021

Coverage Standards will be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options and available peer-reviewed medical literature. If request is for use outside of stated coverage standards, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request.

Chimeric antigen receptor (CAR) T-Cell treatment is a multi-step process including collection, infusion, and recovery. Treatment will only be approved once per member lifetime. CAR-T requests will be evaluated for medical necessity and reviewed on a case by case basis for all Health First Colorado Members based on the following:

I. Kymriah (Tisagenlecleucel)

1. Medical records and treating hematologist/oncologist provide testing to confirm member has one of the following diagnoses and prior treatment experience has been documented:
    a. For member age 18 years and older, Large B-cell lymphoma relapsed or refractory (r/r) disease after two or more lines of systemic therapy (including an anti-CD20 antibody and an anthracycline), including one of the following (i.-iii.), OR relapsed after autologous hematopoietic stem cell transplantation (HSCT)
        i. Diffuse large B-cell lymphoma (DLBCL), not otherwise specified
        ii. High grade B-cell lymphoma
        iii. DLBCL arising from follicular lymphoma
    b. For member age less than age 26 years B-cell precursor acute lymphoblastic leukemia (ALL), refractory or in second or later relapse

2. Prior to treatment:
    a. Member will receive Lymphodepleting (LD) chemotherapy:
        i. Provide LD chemotherapy that member will receive including drug, dose, route frequency and duration prior to treatment with Kymriah.
    b. Member's parent or caretaker/guardian has been informed of anticipated benefits, risks and expectations with treatment including, but not limited to the following:
        i. Remission, Cytokine Release Syndrome (CRS), neurological toxicities, serious infections, hypogammaglobulinemia, prolonged cytopenia, and manufacturing failure

   c. Member has adequate organ, cardiac, and pulmonary function (must meet established criteria/measures) to receive full therapy
   d. Member has been screened for hepatitis B virus, hepatitis C virus, and HIV

3. Treating and prescribing provider(s) attest to the following:
   a. Provider is a hematologist/oncologist experienced in treating with CAR-T therapy
   b. The hospital or associated clinic where the treatment will occur is specially certified per the drug manufacturer and in compliance with the KYMRIAH REMS program for the treatment (including immediate on-site access to tocilizumab)
   c. Member has appropriate labs completed prior to Kymriah treatment for monitoring during and after treatment

4. Treatment location for administration of Kymriah is provided (inpatient, outpatient hospital).

5. Member must *not* have any of the following:
   a. For adult members with Large B-cell lymphoma r/r, member does not have primary central nervous system lymphoma

References:

1. Maude SL, Laetsch TW, Buechner J, et. al. Tisagenlecleucel in Children and Young Adults with B-Cell Lymphoblastic Leukemia. N Engl J Med. 2018;378(5):439-448. doi: 10.1056/NEJMoa1709866.
2. Schuster SJ, Bishop MR, Tam CS, et. al. Tisagenlecleucel in Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma. N Engl J Med. 2019;380(1):45-56. doi: 10.1056/NEJMoa1804980.
3. ClinicalTrials.gov. Study of Efficacy and Safety of CTL019 in Pediatric ALL Patients (ENSIGN). 2020; https://clinicaltrials.gov/ct2/show/study/NCT02228096. Accessed December 16, 2020.
4. Kymriah [package insert]. East Hanover, NJ; Novartis. May 2018.

II. Yescarta (Axicabtagene Ciloleucel)

1. Medical records and treating hematologist/oncologist provide testing to confirm member has one of the following diagnoses and prior treatment experience:
    a. Diagnosis: For member age 18 years and older, relapsed or refractory disease after two or more lines of systemic therapy
        i. diffuse large B-cell lymphoma (DLBCL), not otherwise specified
        ii. primary mediastinal large B-cell lymphoma
        iii. high grade B-cell lymphoma
        iv. DLBCL arising from follicular lymphoma
        v. Follicular lymphoma
            1. Continued approval for this indication is contingent upon verification and description of clinical benefit in confirmatory trial(s).
    b. Treatment regimens:
        i. The lymphoma has not responded to first line chemotherapy
        ii. The lymphoma has not responded to second or greater lines of chemotherapy, or
        iii. The lymphoma has relapsed within 12 months of an autologous hematopoietic stem cell transplant (HSCT)

2. Prior to treatment:
    a. Member will receive Lymphodepleting (LD) chemotherapy:
        i. Provide LD chemotherapy that member will receive including drug, dose, route frequency and duration prior to treatment with Yescarta.
    b. Member's parent or caretaker/guardian has been informed of anticipated benefits, risks and expectations with treatment including but not limited to the following
        i. Remission, post treatment occurrence of secondary malignancy, cytokine release syndrome, neurologic toxicity, and hypogammaglobulinemia
    c. Member has adequate organ, cardiac, and pulmonary function (must meet established criteria/measures) to receive full therapy.
    d. Member has been screened for hepatitis B virus, hepatitis C virus, and HIV

3. Treating and prescribing provider(s) attest to the following:
    a. Provider is a hematologist/oncologist experienced in treating with CAR-T therapy
    b. The hospital facility or associated clinic where the treatment will occur is specially certified per the drug manufacturer and in compliance with the YESCARTA REMS program for the treatment (including immediate on-site access to tocilizumab)
    c. Member has appropriate labs completed prior to Yescarta treatment for monitoring during and after treatment

4. Treatment location for administration of Yescarta is provided (inpatient, outpatient hospital).

5. Member must *not* have any of the following:
    a. History of primary central nervous system lymphoma

b. Administration of live virus vaccination to member at least 6 weeks prior to therapy, during therapy, and until recovery of immune system post-CAR-T therapy
c. Active infection or inflammatory disorder
d. History of prior allogeneic HSCT

References:

1. Locke FL, Ghobadi A, Jacobson CA, et al. Long-term safety and activity of axicabtagene ciloleucel in refractory large B-cell lymphoma (ZUMA-1): a single-arm, multicentre, phase 1-2 trial. *Lancet Oncology.* 2019;20(1):31-42. doi: https://dx.doi.org/10.1016/S1470-2045(18)30864-7.

2. Yescarta [package insert]. Santa Monica, CA; Kite Pharma, Inc. 2021.